

SETTLEMENT AGREEMENT

This Settlement Agreement (Agreement) is entered into among the United States of America, acting through the United States Department of Justice and on behalf of the United States Department of Veterans Affairs (VA) and the United States Department of Defense, Defense Logistics Agency, Department of the Navy, Department of the Air Force, and Department of the Army (DoD) (collectively the United States); Medtronic plc, Medtronic, Inc., Medtronic USA, Inc., and Medtronic Sofamor Danek USA, Inc. (collectively Medtronic); and Relators Samuel Adam Cox, III, Meayna Phanthavong, and Sonia Adams (hereafter collectively referred to as the Parties), through their authorized representatives.

RECITALS

A. The government alleges that Medtronic submitted or caused to be submitted claims for payment for medical devices to VA and DoD hospitals and other entities.

B. On October 5, 2012, Relators Samuel Adam Cox, III, Meayna Phanthavong, and Sonia Adams filed a *qui tam* action in the United States District Court for the District of Minnesota captioned *United States of America ex rel. Samuel Adam Cox, III, Meayna Phanthavong, and Sonia Adams v. Medtronic, Inc., Medtronic USA, Inc., and Medtronic Sofamor Danek USA, Inc.*, civil action no. 12-sc-2562 PAM/JSM, pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3730(b) (the Civil Action). Relators alleged that Medtronic violated the False Claims Act by submitting false claims for payment for certain products to the United States under the Trade Agreements Act of 1979 (TAA), 19 U.S.C. §§ 2501 to 2581, which generally requires

that products sold to the United States above a threshold dollar value be made in the United States or a designated country, unless the Act provides otherwise.

C. The government alleges that from January 1, 2007, to December 31, 2013, and, for the Patient Assistant accessory sold together with other devices under Medtronic product number LNQ11 from January 1, 2014, to September 30, 2014, Medtronic made claims for payment to the DoD and VA for certain products it impliedly or expressly certified complied with country of origin requirements in the TAA and Buy American Act (BAA), 41 U.S.C. §§ 8301 to 8305, including but not limited to certain surgical instruments and other devices used in spine surgery, certain accessories to the NIM Eclipse device, the LNQ11 Patient Assistant accessory, and certain models of anchoring sleeves packaged with cardiac leads. The United States alleges that Medtronic sold products to the VA and DoD during those time periods, as set forth in the foregoing sentence, that did not comply with Medtronic's country of origin certifications. That conduct is referred to below as the Covered Conduct.

D. Medtronic denies the allegations in Paragraphs A-C and the Relators' allegations in the Civil Action.

E. This Settlement Agreement is neither an admission of liability by Medtronic nor a concession by the United States that its claims are not well founded.

F. Relators claim entitlement under 31 U.S.C. § 3730(d) to a share of the proceeds of this Settlement Agreement and to Relators' reasonable expenses, attorneys' fees and costs.

To avoid the delay, uncertainty, inconvenience, and expense of protracted litigation of the above claims, and in consideration of the mutual promises and obligations of this Settlement Agreement, the Parties agree and covenant as follows:

TERMS AND CONDITIONS

1. Medtronic shall pay to the United States Four Million Four Hundred and Ten Thousand Dollars (\$4,410,000) (Settlement Amount) by electronic funds transfer no later than April 30, 2015, pursuant to written instructions to be provided by the United States Attorney's Office for the District of Minnesota.

2. Conditioned upon the United States receiving the Settlement Amount from Medtronic and as soon as feasible after receipt, the United States shall pay to Relators Seven Hundred Forty Nine Thousand Seven Hundred Dollars (\$749,700) by electronic funds transfer.

3. Subject to the exceptions in Paragraph 5 (concerning excluded claims) below, and conditioned upon Medtronic's full payment of the Settlement Amount, the United States releases Medtronic from any civil or administrative monetary claim the United States has for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812; or the common law theories of breach of contract, payment by mistake, unjust enrichment, and fraud.

4. Subject to the exceptions in Paragraph 5 below, and conditioned upon Medtronic's full payment of the Settlement Amount, Relators, for themselves, and for their heirs, successors, attorneys, agents, and assigns, release Medtronic from any civil

monetary claim the Relators have on behalf of the United States for the Covered Conduct under the False Claims Act, 31 U.S.C. §§ 3729-3733.

5. Notwithstanding the releases given in paragraphs 3 and 4 of this Agreement, or any other term of this Agreement, the following claims of the United States are specifically reserved and are not released:

- a. Any liability arising under Title 26, U.S. Code (Internal Revenue Code);
- b. Any criminal liability;
- c. Except as explicitly stated in the Agreement, any administrative liability, including the suspension and debarment rights of any federal agency;
- d. Any liability to the United States (or its agencies) for any conduct other than the Covered Conduct;
- e. Any liability based upon obligations created by this Agreement;
- f. Any liability for express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services;
- g. Any liability for failure to deliver goods or services due;
- h. Any liability for personal injury or property damage or for other consequential damages arising from the Covered Conduct; and
- i. Any liability of individuals.

6. Relators and their heirs, successors, attorneys, agents, and assigns shall not object to this Agreement but agree and confirm that this Agreement is fair, adequate, and

reasonable under all the circumstances, pursuant to 31 U.S.C. § 3730(c)(2)(B).

Conditioned upon Relators' receipt of the payment described in Paragraph 2, Relators and their heirs, successors, attorneys, agents, and assigns fully and finally release, waive, and forever discharge the United States, its agencies, officers, agents, employees, and servants, from any claims arising from the filing of the Civil Action or under 31 U.S.C. § 3730, and from any claims to a share of the proceeds of this Agreement and/or the Civil Action.

7. Relators, for themselves and for their heirs, successors, attorneys, agents, and assigns, release Medtronic, and its officers, agents, and employees, from any liability to Relators arising from the filing of the Civil Action or in connection with the Covered Conduct under the False Claims Act or the common law, except that notwithstanding the release given in Paragraph 4 of this Agreement and in this Paragraph, the following claims of Relators are specifically reserved and are not released: Relators' claims under 31 U.S.C. § 3730(d) for reasonable expenses, attorneys' fees, and costs.

8. Medtronic waives and shall not assert any defenses Medtronic may have to any criminal prosecution or administrative action relating to the Covered Conduct that may be based in whole or in part on a contention that, under the Double Jeopardy Clause in the Fifth Amendment of the Constitution, or under the Excessive Fines Clause in the Eighth Amendment of the Constitution, this Agreement bars a remedy sought in such criminal prosecution or administrative action. Nothing in this paragraph or any other provision of this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

9. Medtronic fully and finally releases the United States, its agencies, officers, agents, employees, and servants, from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that Medtronic has asserted, could have asserted, or may assert in the future against the United States, its agencies, officers, agents, employees, and servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

10. Medtronic fully and finally releases the Relators from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) that it has asserted, could have asserted, or may assert in the future against the Relator, related to the Covered Conduct and the Relators' investigation and prosecution thereof.

11. a. Unallowable Costs Defined: All costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47) incurred by or on behalf of Medtronic, and its present or former officers, directors, employees, shareholders, and agents in connection with:

- (1) the matters covered by this Agreement;
- (2) the United States' audit(s) and civil investigation(s) of the matters covered by this Agreement;
- (3) Medtronic's investigation, defense, and corrective actions undertaken in response to the United States' audit(s) and civil investigation(s) in connection with the matters covered by this Agreement (including attorney's fees);
- (4) the negotiation and performance of this Agreement; and

(5) the payment Medtronic makes to the United States pursuant to this Agreement and any payments that Medtronic may make to Relators, including costs and attorney's fees, are unallowable costs for government contracting purposes (hereinafter referred to as Unallowable Costs).

b. Future Treatment of Unallowable Costs: Unallowable Costs will be separately determined and accounted for by Medtronic, and Medtronic shall not charge such Unallowable Costs directly or indirectly to any contract with the United States.

c. Treatment of Unallowable Costs Previously Submitted for Payment: Within 90 days of the Effective Date of this Agreement, Medtronic shall identify and repay by adjustment to future claims for payment or otherwise any Unallowable Costs included in payments previously sought by Medtronic or any of its subsidiaries or affiliates from the United States. Medtronic agrees that the United States, at a minimum, shall be entitled to recoup from Medtronic any overpayment plus applicable interest and penalties as a result of the inclusion of such Unallowable Costs on previously-submitted requests for payment. The United States, including the Department of Justice and/or the affected agencies, reserves its rights to audit, examine, or re-examine Medtronic's books and records and to disagree with any calculations submitted by Medtronic or any of its subsidiaries or affiliates regarding any Unallowable Costs included in payments previously sought by Medtronic, or the effect of any such Unallowable Costs on the amount of such payments.

12. This Agreement is intended to be for the benefit of the Parties only. The Parties do not release any claims against any other person or entity.

13. Upon receipt of the payment described in Paragraph 1, above, the Parties shall promptly sign and file in the Civil Action a Joint Stipulation of Dismissal of the Civil Action with prejudice pursuant to Rule 41(a)(1), reserving, if it remains unresolved, the issue of the Relators' attorneys' fees, costs, and expenses as described in Paragraph 7 above.

14. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

15. Each party and signatory to this Agreement represents that it freely and voluntarily enters in to this Agreement without any degree of duress or compulsion.

16. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Minnesota. For purposes of construing this Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

17. This Agreement constitutes the complete agreement between the Parties. This Agreement may not be amended except by written consent of the Parties.

18. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the persons and entities indicated below.

19. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.
20. This Agreement is binding on Medtronic's successors, transferees, heirs, and assigns.
21. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.
22. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.
23. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: 3-16-2015

BY: 

ANN M. BILDTSEN
Assistant United States Attorney
United States Attorney's Office
District of Minnesota

DEFENDANTS

DATED: _____

BY: _____

JOAN D. HUMES
VP and Deputy General Counsel
Medtronic plc

DATED: _____

BY: _____

DULCE FOSTER
Fredrikson & Byron, P.A.
Counsel for Medtronic plc, Medtronic, Inc.,
Medtronic USA, Inc., and Medtronic Sofamor
Danek USA, Inc.

RELATORS

DATED: _____

BY: _____

SAMUEL COX, III

DATED: _____

BY: _____

SONIA ADAMS

DATED: _____

BY: _____

MEANYA PHANTHAVONG

DATED: _____

BY: _____

ROSS BROOKS
GRANT MORRIS
VINCE MCKNIGHT
Sanford Heisler, LLP
Counsel for Relators

19. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

20. This Agreement is binding on Medtronic's successors, transferees, heirs, and assigns.

21. This Agreement is binding on Relators' successors, transferees, heirs, and assigns.

22. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public.

23. This Agreement is effective on the date of signature of the last signatory to the Agreement (Effective Date of this Agreement). Facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

THE UNITED STATES OF AMERICA

DATED: _____

BY: _____

ANN M. BILDTSSEN
Assistant United States Attorney
United States Attorney's Office
District of Minnesota

DEFENDANTS

DATED: 3-14-15

BY: Joan D. Humes

JOAN D. HUMES
VP and Deputy General Counsel
Medtronic plc

DATED: 3-16-15


BY: _____

DULCE FOSTER
Fredrikson & Byron, P.A.
Counsel for Medtronic plc, Medtronic, Inc.,
Medtronic USA, Inc., and Medtronic Sofamor
Danek USA, Inc.

RELATORS

DATED: _____

BY: _____
SAMUEL COX, III

DATED: _____

BY: _____
SONIA ADAMS

DATED: _____

BY: _____
MEANYA PHANTHAVONG

DATED: _____

BY: _____
ROSS BROOKS
GRANT MORRIS
VINCE MCKNIGHT
Sanford Heisler, LLP
Counsel for Relators

Danek USA, Inc.

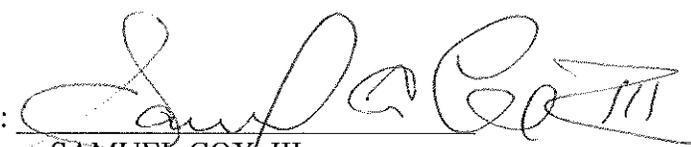
DATED: _____

BY: _____

DULCE FOSTER
Fredrikson & Byron, P.A.
Counsel for Medtronic plc, Medtronic, Inc.,
Medtronic USA, Inc., and Medtronic Sofamor
Danek USA, Inc.

RELATORS

DATED: 03/16/2015

BY: 

SAMUEL COX, III

DATED: _____

BY: _____

SONIA ADAMS

DATED: _____

BY: _____

MEANYA PHANTHAVONG

DATED: _____

BY: _____

ROSS BROOKS
GRANT MORRIS
VINCE MCKNIGHT
Sanford Heisler, LLP
Counsel for Relators

Danek USA, Inc.

DATED: _____

BY: _____

DULCE FOSTER
Fredrikson & Byron, P.A.
Counsel for Medtronic plc, Medtronic, Inc.,
Medtronic USA, Inc., and Medtronic Sofamor
Danek USA, Inc.

RELATORS

DATED: _____

BY: _____

SAMUEL COX, III

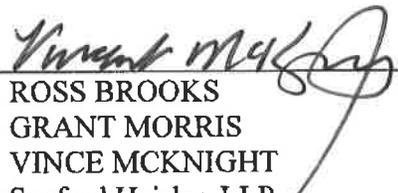
DATED: 3/16/15

BY: 
SONIA ADAMS

DATED: 3/16/15

BY: 
MEANYA PHANTHAVONG

DATED: 3/16/15

BY: 
ROSS BROOKS
GRANT MORRIS
VINCE MCKNIGHT
Sanford Heisler, LLP
Counsel for Relators